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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,016	05/15/2001	Jane C. Hirsh	21720	4877

535 7590 07/16/2002

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/858,016	HIRSH ET AL	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on th cover sh et with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-19,22-29 and 32* is/are pending in the application.

4a) Of the above claim(s) *4,20,21,30 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-19,22-29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application

Applicant's election with traverse of Group I in Paper No. 5 is acknowledged. Further, applicant's election of species of tablet formulation is acknowledged. The traversal is on the ground(s) that the restriction of the pharmaceutical composition and the method of administration is improper since both invention I and II may or may not have signaling methods. This is not found persuasive because Group II is directed toward method claims that have distinct steps. The signaling means was an example of one of the distinctive steps. Group I is directed toward composition claims and intended administration is not considered.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-3, 5-19, 22-29, and 32 are included in the prosecution of this application.

Claims 4, 20-21, and 30-31 are withdrawn from prosecution as being non-elected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "first pass metabolism" in claim 26 is unclear and further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 8-11, and 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Barclay et al (5,053,032).

Barclay et al disclose an osmotic device for delivering a beneficial agent. Barclay's tablet houses two regions, one for buccal administration of a drug and a second region for delivering a drug to the GI tract (Note abstract, col. 8, lines 28-51). Further, the tablet contains a signaling in the form of a flavoring agent or coloring agent that alerts the patient that the buccal administration dosage has been delivered and the remainder may be swallowed (col. 3, lines 57-68, col. 5, lines 25-55). The reference discloses several drugs (analgesics) that are suitable for the delivery device on column 10, line 50 to column 11, lines 35). Barclay discloses the process of making the device and compression of the layers (example 1). Sodium carbonate is taught in the osmotic device in example 3.

Claims 1, 2, 3, 5, 7, 10, 14, 16-18, 27, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (5558879).

Chen et al discloses a controlled release device that has a compressed core containing a medicament, a membrane coating for sustained delivery, a second coating for immediate release of a medicament, and an outer coating layer (Note abstract and examples). Chen et al teach antihistamine (pseudoephedrine), instant polymers, glidants, and excipients are taught in the formulation (examples).

* Note that the recitation of "capable of intraoral administration" and "capable of oral administration" are intended use and are not given patentable weight for a composition claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-5, 7, 12-24, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al (5,053,032) in combination with Jordan et al (4814181).

As set forth above, Barclay et al disclose an osmotic device for delivering a beneficial agent. Barclay's tablet houses two regions, one for buccal administration of a drug and a second region for delivering a drug to the GI tract (Note abstract, col. 8, lines 28-51). Further, the tablet contains a signaling in the form of a flavoring agent or coloring agent that alerts the patient that the buccal administration dosage has been delivered and the remainder may be swallowed (col. 3, lines 57-68, col. 5, lines 25-55).

The reference discloses several drugs, such as analgesics, that are suitable for the delivery device on column 10, line 50 to column 11, lines 35). Barclay discloses the process of making the device and compression of the layers (example 1). Barclay discloses buccal administration can be formulated to administer the drug from .5 to 12 hours (col. 7,lines 34-38). Further, the reference teaches the device to be formulated to withstand the conditions of sucking and chewing by adding a gelling or suspending agent (col. 11, lines 53-65).

Barclay et al does not specifically teach the method of making sustained release and fast release dosages.

Jordan et al teach a dosage form containing a fast agent delivery and a slow agent delivery. Jordan teaches the method of making fast releasing layers and slow releasing layers by manipulating the components in the composition to obtain the desired delivery rate col.4, line 53 to col. 7, line 20). The fast release lamina is taught to deliver in the first hours of operation and the slow releasing lamina is taught to release between 1.5 to 14 hours (col. 4, line 36 to col. 5, lines 37). Jordan teaches the instant polymers such as PEG and HPMC.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Barclay et al and Jordan et al since Jordan et al teaches the manipulation of components in a dosage form to vary the release rates and Barclay et al teaches a method of a signaling system for buccal and GI delivery of a drug. Thus, yielding a dosage form that releases active agents at

different rates and regions and alerts the patient of where to place the pharmaceutical preparation.

Claims 4-5, 7, 12-24, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al (5,053,032) in combination with Faour et al (6004582).

As set forth above, Barclay et al disclose an osmotic device for delivering a beneficial agent. Barclay's tablet houses two regions, one for buccal administration of a drug and a second region for delivering a drug to the GI tract (Note abstract, col. 8, lines 28-51). Further, the tablet contains a signaling in the form of a flavoring agent or coloring agent that alerts the patient that the buccal administration dosage has been delivered and the remainder may be swallowed (col. 3, lines 57-68, col. 5, lines 25-55). The reference discloses several drugs that are suitable for the delivery device on column 10, line 50 to column 11, lines 35). Barclay discloses the process of making the device and compression of the layers (example 1). Barclay discloses buccal administration can be formulated to administer the drug from .5 to 12 hours (col. 7,lines 34-38). Further, the reference teaches the device to be formulated to withstand the conditions of sucking and chewing by adding a gelling or suspending agent (col. 11, lines 53-65).

Barclay et al does not specifically teach the method of making sustained release and fast release dosages.

Faour et al disclose a multi-layered osmotic device that delivers an active agent in the external coat and a second active agent in the core. The active agents can be

similar or different. (Note abstract) The osmotic coat includes a compressed core with an active agent, a semi-permeable membrane, an inert water-soluble polymer coat, and an external coat (col. 3, lines 51-67). Faour et al teaches the active agents may be released in a delayed, sustained, or rapid rate (col. 5, lines 62-64). Faour et al discusses having a controlled and continuous release of the core active and an immediate release of the external active (col. 3, lines 51-67). Further, the reference teaches the extent to which the active agent is released depends on variables such as permeability of the semi-permeable membrane and the magnitude of the osmotic pressure gradient. The osmotic device can deliver the external active in the stomach and the core active in the intestine (col. 5, lines 30-56). Faour et al teach that the external coat may be applied by spraying or compressing the coat over the core or any other method known to an ordinary practioner in the art (col. 6, lines 11-23). Further, it is taught that the active agent will vary according to the identity, physical properties of the drug, the desired effect of the active, and the physiological condition to be treated (col.6, lines 46-53 and col.9, lines 34-36). The reference teaches using flavor or colors in the preparation (col. 11, lines 45-66) and the dosage form can deliver to the buccal region, GI tract, amount others (col. 4, lines 35-42). Faour et al provides examples of the composition of the osmotic device (Note examples.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Barclay et al and Faour et al since Faour et al teaches the manipulation of components in a dosage form to vary the release rates and Barclay et al teaches a method of a signaling system for buccal and

GI delivery of a drug. Thus, yielding a dosage form that releases active agents at different rates and regions and alerts the patient of where to place the pharmaceutical preparation.

Conclusion

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

ALLEN J. ROBINSON
PRIMARY EXAMINER

SSG
July 13, 2002